

## REMARKS

Claims 1-26, 29-36, 38, 39 and 42-54 are pending in the subject application. Claims 1, 2, 16, 26, 29, 42, 44, 45, and 46 are amended. The amendments are supported by the specification as filed (e.g. see page 5, lines 14-15), and no new matter is presented. Favorable reconsideration in light of the remarks which follow is respectfully requested.

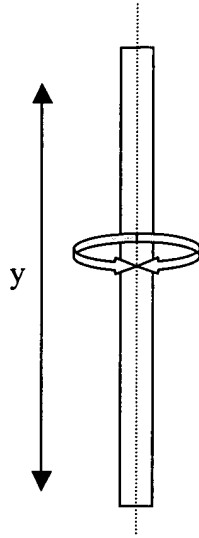
### 35 U.S.C. §102 Rejection

Claims 1-26, 29-36, 38-39, 42, 43, 46 and 48-54 stand rejected under 35 U.S.C. §102(b) as being anticipated by Madhani et al (6,786,896). Applicants respectfully traverse.

## CLAIM 1

Applicants recite, in independent claim 1, an apparatus for placing a proximal portion of a penetrating member in a target area. The apparatus comprises a first arm configured and arranged to rotatably support the penetrating member about the translational axis of the penetrating member; a first drive mechanism coupled to the first arm and configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member along its translational axis in a direction towards the target area; and a second drive mechanism coupled to the penetrating member and configured and arranged so as to cause the penetrating member to rotate about the translational axis of the needle. The first arm and first drive mechanism are coupled to the manipulation device such that the manipulation device can position the apparatus in proximity to the entry point of the object containing the target area.

As set forth by Applicants, the long axis of the penetrating member is its translational axis (see page 5, lines 14-15). This is the axis that runs along the length of the penetrating member (the penetrating member represented below as the rectangle, and the translational axis shown by the dotted line). Applicants' apparatus provides longitudinal motion of the penetrating member along its translational axis (as shown below by the arrow labeled y) and rotational motion about its translational axis (as shown below by the curved arrow).



Applicants respectfully submit that Madhani et al at least does not teach or suggest an apparatus having first arm configured and arranged to rotatably support a penetrating member about the translational axis of the penetrating member, and a second drive mechanism coupled to the penetrating member and configured and arranged so as to cause the penetrating member to rotate about the translational axis of the needle.

Contrary to the Office's assertion, the wrist unit 304 ("first arm") is not configured and arranged to rotatably support the tool shaft 312 ("penetrating member") about the translational axis of the penetrating member. The wrist unit 304 includes carriage 310 which "runs on two 4 mm stainless steel rails" (col. 14, lines 63-64). The wrist unit 368 of the tool shaft 312 is held to the carriage by flexure clamp 366, and the tool shaft is further supported by support 370. However, this arrangement does not allow for the carriage 310 to rotate about the translational axis of the tool shaft 312, which could result in rotation of tool shaft 312 about its translational axis. The two rails on which carriage 310 runs would prevent such motion. Further, there is no teaching or suggestion that the tool shaft 312 itself is held rotatably by the flexure clamp 366 and support 370, nor is there any teaching or suggestion that the tool shaft 312 is otherwise rotatable about its translational axis. The only rotation about the translational axis of the tool shaft 312 is by the wrist 314. As set out by Madhani et al., "The first rotary joint of the wrist, joint 3, rolls

the entire wrist 314 around axis 3, which is coincident with axis 2. The position of joint 3 is indicated by angular displacement  $q_3$ " (col. 15, lines 53-56; Fig. 2)

Thus, contrary to the Office's assertion, figs. 2-3 do not "disclose element 312 has some form of rotation which is capable to cause the penetrating member to rotate about the longitudinal axis of the penetrating member". Rotation, shown by  $q_3$  (Fig. 2) is rotation of the entire wrist 314 about axis 3 (coincident with axis 2) not rotation of tool shaft 312. Fig. 3 further does not show any type of rotation of tool shaft 312 about its long (translational axis).

Accordingly, claim 1 is patentable over Madhani et al. Claims 49 and 52 depend from claim 1 and, likewise, are patentable over Madhani et al. Reconsideration and withdrawal of the rejection is respectfully requested.

#### **CLAIM 16**

Applicants recite, in independent claim 16, an apparatus for placing a proximal portion of a penetrating member in a target area comprising a first arm configured and arranged to rotatably support the penetrating member about the translational axis of the penetrating member; a first drive mechanism coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area; wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates.

Applicants respectfully submit that Madhani at least does not teach or suggest an apparatus for placing a proximal portion of a penetrating member in a target area comprising a first arm configured and arranged to rotatably support the penetrating member about the translational axis of the penetrating member.

As set forth above, Madhani does not teach or suggest rotation of tool shaft 312 (“penetrating member”) about its translational axis. The Office’s citation of figs. 2-3 as support for its’ assertion regarding alleged rotation of tool shaft 312 does not teach or suggest rotation of tool shaft 312 about its translational axis. As set forth above and as explicitly stated by Madhani, “The first rotary joint of the wrist, joint 3, rolls the entire wrist 314 around axis 3, which is coincident with axis 2. The position of joint 3 is indicated by angular displacement  $q_3$ ” (col. 15, lines 53-56; Fig. 2). Fig. 3 is equally deficient as it does not show any type of rotation of tool shaft 312 about its long (translational axis). There is no teaching or suggestion of rotation of the tool shaft 312 about its translational axis.

Accordingly, claim 16 is patentable over Madhani et al. Claims 2-15 and 17-25 depend from claim 16 and, likewise, are patentable over Madhani et al. Reconsideration and withdrawal of the rejection is respectfully requested.

#### **CLAIM 26**

Applicants recite, in independent claim 26, an apparatus for placing a proximal portion of a penetrating member in a target area comprising a first arm configured and arranged to rotatably support the penetrating member about the translational axis of the penetrating member; a first drive mechanism coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member along its translational axis in a direction towards the target area; a second drive mechanism coupled to the penetrating member and being configured and arranged so as to cause the penetrating member to rotate about the translational axis of the penetrating member; wherein the second drive mechanism comprises a gear member secured to the penetrating member and being mechanically coupled to a motor such that operation of the motor causes the penetrating member to rotate about its translational axis.

Madhani et al. at least fails to teach or suggest a first arm configured and arranged to rotatably support the penetrating member about the translational axis of the penetrating member, a second drive mechanism coupled to the penetrating member and being configured and arranged

so as to cause the penetrating member to rotate about the translational axis of the penetrating member, the second drive mechanism comprising a gear member secured to the penetrating member and being mechanically coupled to a motor such that operation of the motor causes the penetrating member to rotate about its translational axis.

As set forth above, Madhani et al. does not teach or suggest rotation of tool shaft 312 (“penetrating member”) about its translational axis.

Accordingly, claim 26 is patentable over Madhani et al. Claims 27 and 28 depend from claim 26 and, likewise, are patentable over Madhani et al. Reconsideration and withdrawal of the rejection is respectfully requested.

#### **CLAIM 29**

Applicants recite, in independent claim 29, an apparatus for placing a proximal portion of a penetrating member in a target area comprising a first arm configured and arranged to rotably support the penetrating member about the longitudinal axis of the penetrating member; a first drive mechanism coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area; the first drive mechanism including a linear guide configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates; a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm; and a second drive mechanism coupled to the penetrating member and being configured and arranged so as to cause the penetrating member to rotate about the longitudinal axis of the penetrating member.

Madhani et al. at least fails to teach or suggest a first arm configured and arranged to rotably support the penetrating member about the longitudinal axis of the penetrating member, and a second drive mechanism coupled to the penetrating member and being configured and

arranged so as to cause the penetrating member to rotate about the longitudinal axis of the penetrating member.

As set forth above, Madhani et al. does not teach or suggest rotation of tool shaft 312 (“penetrating member”) about its translational axis.

Accordingly, claim 29 is patentable over Madhani et al. Claims 30-36 and 38-41 depend from claim 29 and, likewise, are patentable over Madhani et al. Reconsideration and withdrawal of the rejection is respectfully requested.

#### **CLAIM 42**

Applicants recite, in independent claim 42, an apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body comprising a first arm configured and arranged to rotatably support the needle about the translational axis of the needle; a first drive mechanism coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area; a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm; the first drive mechanism including a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates; a second drive mechanism coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle; wherein the second arm further includes a guide mechanism in which the needle is moveably received.

Madhani et al. at least fails to teach or suggest a first arm configured and arranged to rotatably support the needle about the translational axis of the needle, and second drive mechanism coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle.

As set forth above, Madhani et al. does not teach or suggest rotation of tool shaft 312 (“penetrating member”) about its translational axis.

Accordingly, claim 42 is patentable over Madhani et al. Claim 43 depends from claim 42 and, likewise, is patentable over Madhani et al. Reconsideration and withdrawal of the rejection is respectfully requested.

#### **CLAIM 46**

Applicants recite, in independent claim 46, a method for localizing a proximal portion of a penetrating member in a target area of a body comprising supporting the penetrating member from a first arm, positioning the first arm with respect to the body so the translational axis of the penetrating member passes through the target area; linearly translating the first arm from an initial position to any of a number of other positions spaced from the initial, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area; and rotating the penetrating member about the translational axis of the penetrating member.

Madhani et al. at least fails to teach or suggest a method wherein the penetrating member is rotated about the translational axis of the penetrating member.

As set forth above, Madhani et al. does not teach or suggest rotation of tool shaft 312 (“penetrating member”) about its translational axis.

Accordingly, claim 46 is patentable over Madhani et al. Claim 48 depends from claim 46 and, likewise, is patentable over Madhani et al. Reconsideration and withdrawal of the rejection is respectfully requested.


**CONCLUSION**

It is respectfully submitted that the subject application is in a condition for allowance.  
Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,  
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